



U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

| | | |
|---|------------------------------|-------------------------------|
| Application Number 10/623,290 | Filing Date July 18, 2003 | Docket Number: 1662/611053 |
| Invention Title POLYMORPHIC FORMS OF NATEGLINIDE | Examiner To Be Assigned | Art Unit To Be Assigned |

Address to:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:
Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450 on:

Date: 4-14-04

Signature: Beradette Dienna

1. In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of 37 C.F.R. §§ 1.97 and 1.98 and M.P.E.P. § 609, attorneys for Applicants hereby bring the following references to the attention of the Examiner. These references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b).
2. Since the Patent Office has waived the requirement under 37 C.F.R. § 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003, copies of the U.S. patents and publications listed on the modified PTO Form 1449 are not enclosed. Copies of foreign patent documents and non-patent literature listed on the modified PTO Form 1449 are enclosed.
3. Please note that reaction schemes of some of the foreign language art cited herein is provided in the background section of the invention.
4. It is believed that no fees are due in connection with this Information Disclosure Statement. However, should any fees be due the Commissioner is authorized to charge deposit account number 11-0600 for such fees. A copy of this communication is enclosed for charging purposes.

Dated: Apr. 14, 04

By:

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APR 19 2004

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT
PTO-1449**

ATTY. DOCKET NO.
1662/611053

SERIAL NO.
10/623,290

APPLICANT
Ronit YAHALOMI et al.

FILING DATE
July 18, 2003

GROUP
To Be Assigned

U. S. PATENT DOCUMENTS

| EXAMINER INITIAL | PATENT NUMBER | PATENT DATE | NAME | CLASS | SUBCLASS | FILING DATE* |
|------------------|---------------|-------------------|------------------|-------|----------|--------------|
| | 4,816,484 | March 28, 1989 | Toyoshima et al. | | | |
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| | 2001/0044584 | November 22, 2001 | Kensey | | | |
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FOREIGN PATENT DOCUMENTS

| EXAMINER INITIAL | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION |
|------------------|-----------------|--------------------|---------|-------|----------|-------------|
| | | | | | | YES NO |
| | WO 01/21159 | March 29, 2001 | PCT | | | N/A |
| | WO 02/32854 | Apr. 25, 2002 | PCT | | | Abs. |
| | WO 02/34254 | May 2, 2002 | PCT | | | Abs. |
| | WO 02/34285 | May 2, 2002 | PCT | | | N/A |
| | WO 02/34713 | May 2, 2002 | PCT | | | Abs. |
| | WO 02/40010 | May 23, 2002 | PCT | | | Abs. |
| | WO 03/022251 | March 20, 2003 | PCT | | | N/A |
| | WO 03/076393 | September 18, 2003 | PCT | | | N/A |
| | WO 03/087038 | October 23, 2003 | PCT | | | N/A |
| | WO 03/087039 | October 23, 2003 | PCT | | | Abs. |
| | WO 03/093222 | November 13, 2003 | PCT | | | N/A |
| | 200200360 | July 2, 2002 | SK | | | Abs.* |

*Application has not yet published; however, corresponding PCT application No. WO 01/21159 is enclosed.

OTHER DOCUMENTS

| EXAMINER INITIAL | | AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC. |
|------------------|--|--|
| | | Hiroko Takesada et al., "Structure Determination of Metabolites Isolated from Urine and Bile after Administration of AY4166, a Novel D-Phenylalanine-Derivative Hypoglycemic Agent," <i>Bioorganic & Medicinal Chemistry</i> , Vol. 4, No. 10, 1996, pp. 1771-1781 |
| | | Hisashi Shinkai et al., "N-(Cyclohexylcaronyl)-D-phenylalanines and Related Compounds. A New Class of Oral Hypoglycemic Agents. 2," <i>J. Med. Chem.</i> , Vol 32, 1989, pp. 1436-1441 |
| | | Xue-yan Zhu et al., "Study on Synthesis of Nateglinide," <i>Hecheng Huaxue</i> , Vol. 9, No. 6, 2001, pp. 537-540 |
| | | Li Gang et al., "A New Crystal Form of Nateglinide," <i>Acta Pharmaceutical Sinica</i> , Vol. 36, No. 7, 2001, pp. 532-534 |
| | | Li Gang et al., "Found a New Crystal Structure in Nateglinide by X-ray Powder Diffraction," <i>Chinese Journal of Pharmaceutical Analysis</i> , Vol. 21, No. 5, 2001, pp. 342-344 |
| | | A nateglinide having the enclosed XRD (see fig. 17) was purchased before July 3, 2002 in a foreign country from a supplier in another foreign country. |

| EXAMINER | DATE CONSIDERED |
|---|-----------------|
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |